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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,095	01/08/2001	Lloyd G. Mitchell	A31304-B-A-A 072874.0134	5645
21003	7590	03/04/2004	EXAMINER	
BAKER & BOTTS 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			SULLIVAN, DANIEL M	
			ART UNIT	PAPER NUMBER

1636

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/756,095

Applicant(s)

MITCHELL ET AL.

Examiner

Daniel M Sullivan

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-91 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Non-Final Office Action is a reply to the Amendment and Response of 24 November 2003 filed in response to the Non-Final Office Action mailed 20 May 2003. Claims 1-43 were considered in the 20 May Office Action. Claims 1-24 were canceled, claim 26 was amended and claims 44-91 were added in the 24 November Paper. Claims 25-91 are pending and under consideration.

Priority

Claims 1-24 were denied benefit of the parent applications because there is no support for a target binding domain limited to between 10 and 600 nucleotides in length in the parent applications. Claims 1-24 have been canceled and claims 44-91 have been added. The limitations of claims 44-91 are the same as those of claims 1-24 except that the target binding domain of the claims is limited to between 10 and 14 (claims 44-67), 201 and 600 (claims 44-67), or 15 and 200 (claims 68-91) nucleotides in length.

As the parent applications teach that the binding domain should be "at least 15-30 nucleotides in length" (see below), the disclosures clearly do not support the range of between 10 and 14 nucleotides recited in claims 44-67. Therefore, the claims are not entitled to benefit of the parent applications.

On page 28 of the 24 November Paper, Applicant argues that the disclosure by Mitchell (presumably the 08/766,354 and 09/133,717 applications) supports the limitations of claims 68-91 by disclosing "a nucleic acid molecule comprising a target binding domain of at least 15-30 and up to several hundred nucleotides in length."

This argument has been fully considered but is not deemed persuasive because the parent applications do not contemplate the specific subgenera of target binding domains to which the claims are limited. The disclosure of a genus and a specific example within the subgenus range does not necessarily provide adequate descriptive support for the particular subgenus. To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. MPEP 2163 (II)(b). As there is no explicit or implicit guidance in the parent applications that would lead the skilled artisan to the specific range recited in claims 68-91, the limitation is not supported by the parent applications.

Oath/Declaration

Objection to the declaration is withdrawn in view of the filing of a new declaration.

Drawings

Objection to the drawings is withdrawn in view of the filing of formal drawings.

Response to Amendment

Rejection of claims 1-24 is rendered moot by cancellation of the claims.

Claim Objections

Objection to claim 26 for minor informalities is withdrawn.

Claim Rejections - 35 USC § 112

Rejection of claims 26 and 28 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn.

Double Patenting

Claims 25-27, 29-34, 36 and 37 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5, 9-16, 18-21 23, 25 and 32-34 of U.S. Patent No. 6,013,487. Applicant has agreed to file a terminal disclaimer, if appropriate, once the other outstanding rejections are overcome.

Claims 25-33 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7-13, 15, 25-30, 32 and 33 of U.S. Patent No. 6,083,702. Applicant has agreed to file a terminal disclaimer, if appropriate, once the other outstanding rejections are overcome.

New Grounds

Claim Objections

Claims 37 and 39 are objected to because of the following informalities: The second step in each of the claims is mislabeled step “d)”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 44-91 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

The MPEP states, “[i]f new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. §112, first paragraph-written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).” (MPEP § 2163.06). The MPEP further states, “[w]henever the issue arises, the fundamental factual inquire is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in the application” (*Id.*, § 2163.02). The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996).

The limitations of claims 44-91 are the same as those of claims 1-24 except that the target binding domain of the claims is limited to between 10 and 14 (claims 44-67), 201 and 600 (claims 44-67), or 15 and 200 (claims 68-91) nucleotides in length. Thus, the nucleic acid of the claims is now limited to comprising target binding domains wherein the length of the target binding domains is limited to various subgenera of the range originally set forth in the claims. Applicant urges that the new limitations do not add new matter but does not particularly point out where support for the new ranges can be found in the originally filed application.

Upon reviewing the application, the Examiner can find no explicit teaching of a target binding domain limited to between 10 and 14, 201 and 600, or 15 and 200 nucleotides in length. As discussed above, the disclosure of a genus and a specific example within the subgenus range does not necessarily provide adequate descriptive support for the particular subgenus. To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. As there is no explicit or implicit guidance in the instant application that would lead the skilled artisan to the specific ranges recited in claims 68-91, the limitation is not supported by the application as filed and therefore constitutes new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-31, 36-42 and 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 25, 26, 29, 30, 36, 37, 39 and 40 are indefinite in the recitation of "the target pre-mRNA" in step "b)". There is no antecedent basis for "the target pre-mRNA" in the claims.

Claims 27, 28, 31, 38, 41 and 42 are indefinite insofar as they depend from claims 25, 26, 29, 36, 39 and/or 40.

Claim 63 is indefinite in the recitation of "the translatable protein product". There is no antecedent basis for the phrase in claims 59 or 60, from which claim 63 depends. Amending the claim such that it depends from claim 62 would be remedial.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 38 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 33 of U.S. Patent No. 6,013,487 (hereinafter '487). Although the conflicting claims are not identical, they are not patentably distinct.

Claim 36, from which claim 38 depends, was previously rejected as obvious over claim 32 of the '487 patent because the instant claim differs from the patented claims only in the omission of specific structural limitations. As claim 32 of the '487 patent falls entirely within the

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scope of the instant claim 36, the instant claim is anticipated by the patented claim and would be obvious in view thereof. For these same reasons the additional limitation of a 5' donor site, which set forth in the instant claim 38 would be obvious in view of claim 33 of the '487 patent, which sets forth the same additional limitation and depends from claim 32.

Claims 39-43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28-31 and 33 of U.S. Patent No. 6,083,702 (hereinafter '702). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims differ from the patented claims only in the omission of specific structural limitations or process steps. Claims 28-31 and 33 fall entirely within the scope of the instant claims 39-43, respectively. Therefore, the instant claims are anticipated by the patented claims and would be obvious in view thereof.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 68, 71, 73, 75, 78, 81-83, 86-88 and 91 are rejected under 35 U.S.C. 102(b) as being anticipated by Puttaraju *et al.* (1999) *Nat. Biotechnol.* 17:246-252 (previously made of record).

The limitations of newly added claims 68, 71, 73, 75, 78, 81-83, 86-88 and 91 are the same as those set forth in original claims 1, 4, 6, 8, 11, 14-16, 19-21 and 24, respectively, except that the target binding domain of the claims is limited to between or 15 and 200 nucleotides in length. As described in the 20 May Office Action, Puttaraju *et al.* teaches all of the limitations of original claims 1, 4, 6, 8, 11, 14-16, 19-21 and 24. Furthermore, the target binding domain of Puttaraju *et al.* is 18 nucleotides in length (see especially Figure 1 and the caption thereto, and Table 1) which falls within the range set forth in the new claims. Therefore, Puttaraju *et al.* teaches all of the limitations of the instant claims 68, 71, 73, 75, 78, 81-83, 86-88 and 91; thus, the claims are anticipated by Puttaraju *et al.*

Claims 68, 69, 71-76, 78, 79, 81-84, 86-89 and 91 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitchell (WO 97/22250; previously made of record).

The limitations of newly added claims 68, 69, 71-76, 78, 79, 81-84, 86-89 and 91 are the same as those set forth in original claims 1, 2, 4-9, 11, 12, 14-17, 19, 20-22 and 24, respectively, except that the target binding domain of the claims is limited to between or 15 and 200 nucleotides in length. As described in the 20 May Office Action, Mitchell teaches all of the limitations of original claims 1, 2, 4-9, 11, 12, 14-17, 19, 20-22 and 24. Furthermore, the target binding domain of Mitchell is at least 15-30 and up to several hundred nucleotides in length (see especially the legend for Figure 1 beginning on page 6) which falls within the range set forth in the new claims. Therefore, Mitchell teaches all of the limitations of the instant claims 68, 69, 71-76, 78, 79, 81-84, 86-89 and 91; thus, the claims are anticipated by Mitchell.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DMS


DAVID GUZO
PRIMARY EXAMINER